

REMARKS

Claims 29-52, 54-55, 57 and 59-79 are pending in the application with entry of this amendment. No claim is amended. New claims 74-79 are added. The new claims do not present new matter. *See, e.g.*, p. 4, lines 21-27; p. 11, lines 3-7; p. 11, line 28 – p. 12, line 2 (describing insulative chamber). Reconsideration and allowance of the application, as amended, are respectfully requested.

I. Withdrawn Rejections

Applicants acknowledge that the following rejections were withdrawn following the Amendment submitted on June 26, 2008:

- A. Rejection of claims under 35 U.S.C. §101.
- B. Rejection of claims under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 5,846,210 to Ogawa (“Ogawa”)
- C. Rejection of claims under 35 U.S.C. §103(a) as allegedly being unpatentable over Ogawa in view of U.S. Patent No. 5,669,905 to Scheldrup *et al.* (“Scheldrup”)
- D. Rejection of claims under 35 U.S.C. §103(a) as allegedly being unpatentable over Ogawa in view of U.S. Patent No. 5,669,245 to Guglielmi *et al.* (“Guglielmi”)
- E. Rejection of claims under 35 U.S.C. §103(a) as being allegedly being unpatentable over Ogawa in view of U.S. Patent No. 5,814,062 to Sepetka *et al.* (“Sepetka”).
- F. Rejection of claims under 35 U.S.C. §103(a) as being allegedly being unpatentable over Ogawa in view of U.S. Patent No. 6,296,636 to Cheng *et al.* (“Cheng”).

II. Claims 29-35, 38, 43-52, 54, 59-61, 64-65 and 72 Are Patentable Over Wheelock and Ogawa

Independent claim 29 and dependent claims 30-35, 38, 43-52, 54, 59-61, 64-65 and 72 stand rejected under 35 U.S.C. §103(a) as being allegedly being unpatentable over U.S. Patent No. 6,077,260 to Wheelock *et al.* (“Wheelock”) in view of Ogawa. Applicants respectfully traverse the rejection and respectfully submit that the rejection is moot in view of the deficiencies of the cited references.

Wheelock is a new reference cited to support the rejection. Fig. 1A of Wheelock is reproduced below for reference.

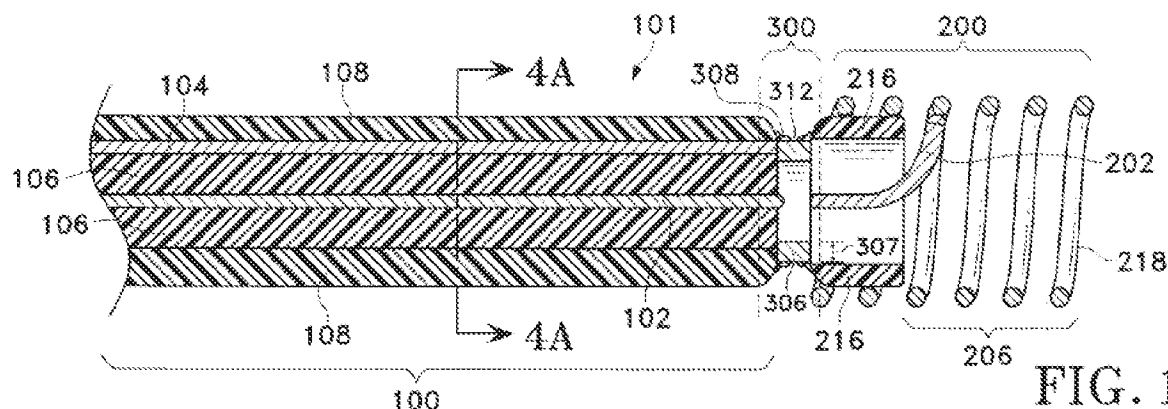


FIG. 1A

With reference to Wheelock, Fig. 1A above, Wheelock describes a wire assembly 101 having a composite core wire 100, an implant 200 and an electrolytically erodible junction 300 there between. Wheelock (col. 4, lines 20-26). The composite core wire 100 includes a first electrically conductive member 102 and a second electrically conductive member 104. Wheelock (col. 4, lines 33-34 and lines 61-65). “Generally speaking, the electrically conductive member (102) is in electrical contact with implant (200).” Wheelock (col. 4, lines 48-50). The implant 200 is “electrically isolated from the second electrically conductive member (104) and the erodible ring (306) but in electrical contact with first electrically conductive member (102). One way in which this may be accomplished is by the use of a third electrically conductive member (202). This third electrically conductive member (202) is insulated from the second electrically conductive member (104), but is in electrical contact with the first electrically conductive member (102) before implant release, and is in electrical contact with an exposed area (206) of the implant...” Wheelock (col. 5, lines 44-45).

Turning to the Office action, it is conceded that Wheelock fails to disclose an electrical measurement device that is configured to monitor an electrical condition, such as impedance, related to the position of the temporary connection while the temporary connection is joined to the delivery member and the implant or the temporary connection being breakable by heat. Office Action (p. 3, para. 1). Thus, it is Applicant’s understanding that it is conceded that Wheelock fails to disclose “the electrical measurement device is configured to monitor an electrical condition related to a position of the temporary connection while the temporary connection is joined to the delivery member and joined to the implant through the insulative member, the electrical condition changing when the temporary connection, joined to the implant, reaches a predetermined location as the delivery member is advanced through the catheter, the

electrical measurement device configured to generate an output signal while the temporary connection is joined to the implant and in response to the changed electrical condition, the output signal indicating that the temporary connection, joined to the implant, has reached the predetermined location” as recited in claim 29.

Wheelock also fails to disclose “a temporary connection joined to a distal end of the delivery member, the insulative member being positioned between and connecting the temporary connection and the implant” as recited in claim 29. It is alleged that the composite core wire 100 disclosed by Wheelock is a “delivery member,” the insulating layer 216 is an “insulative member” and the electrolytic junction 300 is a “temporary connection” as recited in claim 29.

Initially, Applicant notes that while the Office action refers to the insulating layer 216 and an implant (presumably implant 200) as different components, Wheelock actually illustrates and explains that the implant 200 includes (as shown by the top right bracket in Fig. 1) a coil 218 having an exposed area 206, the insulating layer 206 and an electrically conductive member 202. Thus, contrary to what is alleged, the insulating layer 206 is actually part of the implant 200, which is consistent with the fact that Fig. 1A illustrates the insulating layer 206 along sections of the coil 218, which is also part of the implant 200. Also consistent with this conclusion is the fact that Wheelock explains “FIGS. 1A-1C depict a preferred coil implant (218) which has an insulating layer (216)...” Wheelock (col. 5, lines 55-57). Thus, Wheelock specifically explains that the insulating layer 216 is part of the coil implant 218. Accordingly, Office action allegations that are based on the insulating layer 216 being something other than an implant 200 or a coil 218 contradict what is described by Wheelock.

Nevertheless, even if Wheelock is construed in a manner that is not actually described by the cited reference, Wheelock fails to disclose “a temporary connection joined to a distal end of the delivery member, the insulative member being positioned between and connecting the temporary connection and the implant” as recited in claim 29.

Referring to Fig. 1A of Wheelock above, the cited reference describes a different configuration in which the erodible conductive ring 306 of the electrolytic junction 300 is the only structure that actually extends between the distal end of the composite corewire 100 (alleged “delivery member”) and a proximal end of the implant 200. As is well understood, the conductive ring 306, as its name implies, is conductive and, therefore, is not an insulative member. This is consistent with Wheelock explaining “Generally speaking, the electrically

conductive member (102) is in electrical contact with implant (200).” Wheelock (col. 4, lines 48-50). This electrical contact is completed through the non-insulative, conductive ring 306.

The insulating layer 216 is, as its name implies, a layer, and as shown in Wheelock, Fig. 1A, this layer 216 extends along an inner surface of the coil 218 (*i.e.*, along an inner surface of the implant 200). The layer 216, however, is not positioned “between” and does not “connect” the erodible ring 306 and the coil 218. Wheelock (Fig. 1A). The Office Action is understandably silent as to the specific structural configurations recited in claim 29 since the layer 216 cannot support the rejection.

Wheelock also describes different components for connecting the core wire 100 (alleged “delivery member”) and the implant 200. Wheelock explains that the implant 200 and the core wire 100 are in contact with each other when the junction 300 there between is intact, and the protruding distal end of the first electrically conductive member 102 is in contact with a surface 208 of a third electrically conductive member 202. Wheelock (col. 5, line 59 – col. 6, line 10). Notably, this section does not mention the insulating layer 216, consistent with the fact that the insulating layer 216 is used for a different and unrelated purpose, *i.e.*, to electrically isolate the coil 218 from a second electrically conductive member. Wheelock (col. 5, lines 56-58).

Given the particular structural configuration of the insulative “layer” 216 and function thereof as described above, Wheelock teaches away from the “temporary connection joined to a distal end of the delivery member, the insulative member being positioned between and connecting the temporary connection and the implant” as recited in claim 29 since a “layer” along an inner surface of a coil 216, as is well understood in the art, is not intended to be positioned between and connect a temporary connection and an implant, particularly considering that Wheelock describes other connection components.

Thus, while Applicant appreciates that Wheelock may disclose components that have similar names, the structure that is actually disclosed by Wheelock cannot support the rejection and does not apply to claim 29, which recites a temporary connection that is joined to a distal end of the delivery member, an insulative member positioned between the temporary connection and the implant, and the insulating member connecting the temporary connection and the implant.

Ogawa is cited as allegedly disclosing an electrical measurement device that is configured to monitor an electrical condition related to a position of a temporary connection while the temporary connection is joined to the delivery member and to the implant. Office

Action (p. 3, para. 2). Ogawa, however, does not cure the deficiencies of Wheelock discussed above, as explained in detail in the Amendment submitted on June 26, 2008.

As conceded in the Office action mailed on April 4, 2008, Ogawa fails to disclose the structural combination of a catheter, a delivery member, an insulative member, and a temporary connection, the “temporary connection joined to a distal end of the delivery member, the insulative member being positioned between and connecting the temporary connection and the implant” as recited in claim 29. June 26, 2008 Office Action (p. 4). Acknowledgement of these deficiencies is implied by the Office Action citing Wheelock, but Wheelock, as explained above, cannot support the rejection.

As explained in the June 26, 2008 Amendment, with reference to Fig. 1 of Ogawa, this cited reference explains that the guide wire 10 includes a proximal part 11, a flexible part 12 and an X-ray impervious part 13. Ogawa (col. 6, lines 8-11). “The joint member is connected to an end of the X-ray impervious part 13.” Ogawa (col. 6, lines 8-11). A proximal part 15a of the joint member 15 is inserted into a coiled distal part 14 of the guide wire 10 and fixedly connected thereto with an adhesive. Ogawa (col. 6, lines 50-53; Fig. 2). A distal part 15b of the joint member 15 is inserted into a coil portion 16A of the implanted device 16 and fixedly connected thereto with an adhesive. Ogawa (col. 6, lines 62-67; Fig. 2).

With reference to Fig. 6, Ogawa further explains:

FIG. 6 illustrates another embodiment of the present invention. In this embodiment, an electrically insulated **coating 25** is provided **on the peripheral surfaces of the flexible part 12 and distal X-ray impervious part 13** in the guide wire 10. This electrically insulated **coating 25** can be formed by one of various polymers, for example, polyurethane, polyethylene, polypropylene, silicone resins and polyamide resins such as nylon. A hydrophilic polymer coat may be further provided on the coating of this resin. Ogawa (col. 9, lines 35-43) (emphasis added).

According to the medical wire of such a construction, the implanted device 16 can be detached and deposited by applying a monopolar high-frequency current through the guide wire 10 as like in the above-described embodiment. In addition, since almost the entire surface of the guide wire 10, with which the body tissue is brought into contact, is **covered with the electrically insulated coating 25**, the medical wire may be inserted into the patient's body without using any catheter. Ogawa (col. 9, lines 44-52) (emphasis added).

As explained above, parts 12 and 13 are portions of the guide wire 10, and the insulated coating 25 is applied to the peripheral surfaces of part of the guide wire 10.

Accordingly, the joint member 15 is located distally relative to the portions 12 and 13 that are coated with the coating 25, which is on or around portions of the guide wire 10. Ogawa (Fig. 6). Therefore, the insulated coating 25 is not an insulative member that is positioned between a temporary connection and an implant, and the insulated coating 25 does not connect a temporary connection and an implant.

Further, a peripheral insulated “coating” as described by Ogawa, as its name implies, is not suitable for being positioned between and connecting the joint member 15 and implanted device 16, particularly considering that Ogawa specifically explains that the insulative “coating” 25 is used for a specific, different purpose that is not related to the structural configuration recited in claim 29. Ogawa explains that the purpose of the insulated coating 25 is for insertion of the medical wire into a patient’s body without the need for a catheter. Ogawa (col. 6, lines 50-52). Fig. 2 of Ogawa illustrates that the distal end of the joint member 15 is fixedly connected to a proximal portion 16A of the implanted device 16. Thus, the insulated coating 25 is not related to, not suitable for, and not required for, connecting the joint member 15 (the alleged “temporary connection”) and the implanted device 16, particularly considering that Ogawa explains that the joint member 15 is fixedly connected to the guide wire 10 by an adhesive and also fixedly connected to a coil portion of the implanted device 16 by an adhesive.

Therefore, as conceded in the Office Action, and consistent with the deficiencies of Ogawa, this cited reference fails to disclose the “temporary connection joined to a distal end of the delivery member, the insulative member being positioned between and connecting the temporary connection and the implant” as recited in claim 29.

Moreover, given the particular structural configuration of the insulated “coating” 25 and function thereof as described above, Ogawa teaches away from the “temporary connection joined to a distal end of the delivery member, the insulative member being positioned between and connecting the temporary connection and the implant” as recited in claim 29 since a “coating,” as is well understood in the art, is not intended to be positioned between and connect a temporary connection and an implant.

Additionally, since Ogawa actually explains that the purpose of the coating 25 allows elimination of the catheter 20, Ogawa is not applicable to claim 29, which positively recites *inter alia* “a catheter having a proximal end and a distal end...” Thus, Ogawa describes a configuration that is the opposite of the configuration recited in claim 29 and teaches away from

claim 29 since the insulation coating 25 described by Ogawa is used for the purpose of eliminating a positively recited element in claim 29.

In view of these deficiencies and differences, Applicants respectfully submit that independent claim 29 is patentable over Wheelock and Ogawa since the cited references, even if somehow properly combined, fail to disclose each limitation of claim 29. Dependent claims 30-35, 38, 43-52, 54, 59-61, 64-65 and 72 incorporate the elements of claim 29 and, therefore, are also believed patentable over Wheelock and Ogawa. MPEP §2143.03 (If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious). The cited references are also deficient relative to various dependent claims.

Deficiencies of Ogawa with respect to various dependent claims are discussed in the June 26, 2008 amendment.

Applicants again note that the Office action has not specifically addressed claim 64, which recites *inter alia*, “a conductive wire connected between the electrical measurement device and the distal end of the catheter, the electrical measurement device being configured to detect an electrical condition related to a position of the temporary connection, while joined to the implant, in the catheter through the conductive wire” and claim 65, which recites *inter alia* “the conductive wire being positioned through the catheter.” 35 U.S.C. §132; 37 C.F.R. §1.194(c)(2); MPEP §2112. Applicants respectfully request the Examiner to identify, by column and line number, the sections of Wheelock and/or Ogawa that allegedly disclose the components recited in these claims if the rejection of this claim stands following this Amendment.

Claim 72 recites *inter alia* “wherein the output signal is provided to a user, while the temporary connection is joined to the implant, to allow the user to manually initiate breaking of the temporary connection and to release the implant.” It is generally alleged, with reference to a specific section of Ogawa, that Ogawa discloses “allowing the user to initiate breaking of the temporary connection by application of heat and releasing the implant...” Office Action (p. 3, para. 2, lines 14-15). However, the Office Action has cited no section of Ogawa that actually describes allowing a user to decide when to manually initiate breaking of a temporary connection. Rather, Ogawa explains that current for detaching the implanted device is applied. Ogawa (col. 7, line 62 – col. 8, line 6). 35 U.S.C. §132; 37 C.F.R. § 1.194(c)(2); MPEP §2112.

In view of the above remarks, Applicants respectfully submit that the rejection of claims 29-35, 38, 43-52, 54, 59-61, 64-65 and 72 under 35 U.S.C. §103(a) be withdrawn.

III. Claims 36, 41-42, 55, 57 and 66 Are Patentable Over Wheelock, Ogawa and Scheldrup

Dependent claims 36, 41-42, 55, 57 and 66 (which depend from independent claim 29), stand rejected under 35 U.S.C. §103(a) as being unpatentable over Wheelock in view of Ogawa and further in view of Scheldrup. Scheldrup, however, does not cure the substantial deficiencies of Wheelock and Ogawa discussed above. Consequently, no proper combination of these three references discloses each limitation of independent claim 29 and the rejected dependent claims.

Accordingly, Applicants respectfully submit that the rejection of claims 36, 41-42, 55, 57 and 66 under 35 U.S.C. §103(a) be withdrawn. MPEP §2143.03.

IV. Claim 37 Is Patentable Over Wheelock, Ogawa and Palermo

Dependent claim 37 (which depends from independent claim 29), stands rejected under 35 U.S.C. §103(a) as being unpatentable over Wheelock in view of Ogawa and further in view of Palermo. Palermo, however, does not cure the substantial deficiencies of Wheelock and Ogawa discussed above. Consequently, no proper combination of these three references discloses each limitation of independent claim 29 and claim 37.

Accordingly, Applicants respectfully submit that the rejection of claim 37 under 35 U.S.C. §103(a) be withdrawn. MPEP §2143.03.

V. Claim 39 Is Patentable Over Wheelock, Ogawa and Guglielmi

Dependent claim 39 (which depends from independent claim 29), stands rejected under 35 U.S.C. §103(a) as being unpatentable over Wheelock in view of Ogawa and further in view of Guglielmi. Guglielmi, however, does not cure the substantial deficiencies of Wheelock and Ogawa discussed above. Consequently, no proper combination of these three references discloses each limitation of independent claim 29 and claim 39.

Accordingly, Applicants respectfully submit that the rejection of claim 39 under 35 U.S.C. §103(a) be withdrawn. MPEP §2143.03.

VI. Claim 40 Is Patentable Over Wheelock, Ogawa and Sepetka

Dependent claim 40 (which depends from independent claim 29), stands rejected under 35 U.S.C. §103(a) as being unpatentable over Wheelock in view of Ogawa and further in view of Sepetka. Sepetka, however, does not cure the substantial deficiencies of Wheelock and Ogawa discussed above. Consequently, no proper combination of these three references discloses each limitation of independent claim 29 and claim 40.

Accordingly, Applicants respectfully submit that the rejection of claim 40 under 35 U.S.C. §103(a) be withdrawn. MPEP §2143.03.

VII. Claims 62-63 Are Patentable Over Wheelock, Ogawa and Cheng

Dependent claims 62-63 (which depend from independent claim 29), stand rejected under 35 U.S.C. §103(a) as being unpatentable over Wheelock in view of Ogawa and further in view of Cheng. Cheng, however, does not cure the substantial deficiencies of Wheelock and Ogawa discussed above. Consequently, no proper combination of these three references discloses each limitation of independent claim 29 and claims 62-63.

Accordingly, Applicants respectfully submit that the rejection of claims 62-63 under 35 U.S.C. §103(a) be withdrawn. MPEP §2143.03.

VIII. Claims 67-71 and 73 Are Patentable Over Wheelock, Ogawa and Scheldrup

Independent claim 67 and dependent claims 68-71 and 73 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Wheelock in view of Ogawa and further in view of Scheldrup. Applicants respectfully submit that the rejection is moot in view of the above remarks.

Accordingly, Applicants respectfully submit that the rejection of claims 67-71 and 73 under 35 U.S.C. §103(a) be withdrawn. MPEP §2143.03.

IX. New Claims 74-79

Claims 74-79 depend from respective independent claims 29 and 69 and, therefore, are also believed patentable over the cited references. Various cited references are also deficient relative to these claims.

Claims 74 and 75 recite *inter alia* “wherein the catheter and the insulative member form an insulative chamber that prevents or minimizes the amount of current that flows through the delivery member when the delivery member is within the catheter.” In contrast, Wheelock, for example, describes a composite core wire 100 includes several elements including a first electrically conductive member 102 and a second electrically conductive member 104 and explains “Generally speaking, the electrically conductive member (102) is in electrical contact with implant (200)” and that the implant is “in electrical contact with first electrically conductive member (102). One way in which this may be accomplished is by the use of a third electrically conductive member (202). This third electrically conductive member (202) is insulated from the second electrically conductive member (104), but is in electrical contact with the first electrically conductive member (102) before implant release, and is in electrical contact with an exposed

area (206) of the implant...” Wheelock (col. 4, lines 48-50; col. 5, lines 44-45). In this regard, Wheelock also teaches away from these claims since the erodible conductive ring 306 of the electrolytic junction 300 is the only structure that actually extends between the distal end of the composite corewire 100 (alleged “delivery member”) and a proximal end of the implant 200, the implant is in electrical contact with an electrically conductive member, and the cited insulative layer 216 is used for a different purpose that is not related to these claims.

Claims 76 and 77 recite *inter alia* “wherein the temporary connection is insulated from the implant so that electrical current passes to the temporary connection but not the implant.” As discussed above, Wheelock, on the other hand, explains that “Generally speaking, the electrically conductive member (102) is in electrical contact with implant (200)” and that the implant is “in electrical contact with first electrically conductive member (102). One way in which this may be accomplished is by the use of a third electrically conductive member (202). This third electrically conductive member (202) is insulated from the second electrically conductive member (104), but is in electrical contact with the first electrically conductive member (102) before implant release, and is in electrical contact with an exposed area (206) of the implant...” Wheelock (col. 4, lines 48-50; col. 5, lines 44-45). This electrical contact is made through the conductive ring 306 of the electrolytic junction 300 (alleged temporary connection). Thus, Wheelock describes a configuration that is the opposite of the structural configuration recited in these claims and teaches away from these claims.

Claims 78 and 79 recite *inter alia* “the temporary connection having a proximal end and a distal end, the implant having a proximal end and a distal end, wherein the insulative member extends between the distal end of the temporary connection and the proximal end of the implant.” In contrast, Wheelock describes an insulative layer 216 which, as shown in Fig. 1 of Wheelock, extends along an inner surface of a coil 216 and, therefore, does not extend between the distal end of the erodible ring 306 (alleged “temporary connection”) and the proximal end of the coil 206.

CONCLUSION

Applicants respectfully submit that the application is in condition for allowance in view of the forgoing amendments and remarks. If there are any remaining issues that can be resolved by telephone, Applicants invite the Examiner to contact the undersigned at the number indicated below.

Respectfully submitted,

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Dated: August 5, 2009

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